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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,727	08/03/2001	Albert Orfao	3582/49121	5099

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,727	ORFAO, ALBERT	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2005 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: in line 11, "other sample particles" should be replaced with –other particles—to make it consistent with the preamble. Appropriate correction is required.

Claim 14 is objected to because of the following informalities: Applicant should insert –comprised of material—before "selected".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 4, the language "could be passed" does not clearly recite that the sample is actually passed through the chamber. Applicant's argument and Applicant's claims appear to contradict as to what claim 1 requires. Applicant argues, on page 6, lines 1-2 of Applicant's response, that the references do not appear to teach that the large-capturing particles are contained in a chamber through which the sample *is* passed. Thus, it appears that Applicant interprets claim 1 to require that the sample be passed through the chamber. However, in dependent claim 7, Applicant recites passing the sample through a chamber as *optional*. It is unclear as to whether claim 1 requires that the sample be passed through the chamber or whether this is an option. (Moreover, if claim 1 requires that the sample be passed through the chamber, then it appears that dependent claim 7 also has a vagueness issue because it recites that the step of passing the sample through the chamber is an option.)

Claim 1, lines 6-7 recites "said large-capturing particles being larger than 200 um". It is unclear whether this size is referring to diameter or some other dimension. (For examination purposes, the Office will interpret the limitation as if it is referring to diameter.)

Also in claim 1, line 5, "large number" is a relative term lacking a comparative basis, i.e., how large is "large"?

Claim 5 recites the limitation "the isolation/depletion" in line 3. There is insufficient antecedent basis for this limitation in the claim. Although "isolation" has antecedent basis in claim 1, line 1, there is not antecedent basis for "isolation/depletion". Also, it is not clear if Applicant means --isolation and depletion--,

or --isolation or depletion--. (For examination purposes, the Office will interpret the limitation as if Applicant intends to recite "isolation or depletion")

Claim 6 recites the limitation "each set of large-capturing particles" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Also, it is not clear how many sets are recited. (For examination purposes, the Office will interpret the limitation as if it is referring to a plurality of sets.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al., 6,268,222, in view of Ollington et al., 6,010,866, and further in view of Hansen, WO 00/11449.

Chandler discloses a process for isolating molecules, cells and other particles which are specifically bound to a large particle comprising:

incubating a sample (col. 14, lines 64-65, and col. 19, lines 4-13) with at least one set of large-capturing particles (i.e., microparticles, col., 3, line 9) each of said large-capturing particles being able to specifically bind/capture a large number of molecules, cells or other particles contained in the sample (e.g., antigens, nucleic acids,

col. 12, lines 58-64), said large-capturing particles being larger than 200 um (col. 3, lines 11-12, disclosing the particle to be in the claimed range);

analyzing the large-capturing particles containing specifically bound molecules, cells or other particles (col. 15, lines 51-55);

and detaching the molecules, cells or other sample particles of interest from the larger-capturing particles (see col. 16, lines 45-49, disclosing the step of releasing the products of interest after its isolation.)

Although Chandler discloses the step of incubation of a fluid sample with the large-capturing particles (col. 14, lines 64-65, and col. 19, lines 4-13), Chandler does not disclose that the large-capturing particles are contained in a chamber through which the sample could be passed (as claimed by Applicant in claim 1, lines 3-4.) Ollington et al. teaches this limitation.

Ollington et al. teaches a chamber (i.e., within the reaction pipette 114, col. 13, lines 24-28) containing particles with attached antibodies (col. 13, lines 27-28, and col. 6, lines 37-38 and 40-41.) The chamber allows for a sample to be passed (col. 13, lines 26-28) and for incubation of the sample with the particles (col. 13, lines 32-33.) Ollington et al. teaches that non-reacted material will pass through a filter (col. 13, lines 35-38) for subsequent analysis of the filtrate (col. 13, lines 53-55.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Ollington et al. reaction pipette to contain the Chandler capturing particles (generally disclosed by Chandler as being incubated with a fluid sample) because Ollington et al. teaches that the reaction pipette provides the

advantage of convenience in allowing for incubation of capturing particles with a fluid sample as well as filtering out non-reacted material in the sample as would be desirable in the Chandler method.

With respect to claim 17, Ollington et al. discloses incubation in two or more chambers (see column 13, lines 49 through 53.) (The Office notes that Chandler discloses isolation of two or more different types of molecules, cells or other particles, see column 17, lines 44 through 50 and column 24, lines 6 through 10.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize two or more of the reaction pipettes taught by Ollington et al. for isolation of two or more different types of molecules in the Chandler method because Ollington et al. teaches the convenience of using several of the disclosed reaction pipettes.

Chandler also does not disclose the step of sorting from each other the large-capturing particles containing specifically bound molecules, cells or other particles (as recited in claim 1), nor the step of sorting large-capturing particles bound to molecules, cells or other sample particles into Petri dishes or microtiter plates (as recited in claims 9 and 15.) Hansen discloses these limitations. (The Office notes that Chandler teaches that the preferred method to detect, differentiate, sort, quantitate, and/or analyze the analytes in a sample is flow cytometry; see column 4, lines 55 through 58.)

Hansen teaches a particular type of flow cytometer (see first sentence of abstract) for analyzing and dispensing objects (including objects having a diameter larger than 200 um, see page 19, lines 4-7) using sorting actuators (20', see page 26, lines 8-11) for diverting a portion of the sample stream into different destinations (page

26, line 9), such as into different microtiter plates (page 22, lines 17-18), based on a signal from a detector, such as a detector for a fluorescent label (page 25, lines 11-16), and Hansen also discloses a processor (page 23, line 2.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Hansen flow cytometer for the flow cytometry generally disclosed in the Chandler method because Hansen teaches that the disclosed flow cytometer provides the advantage of convenience in performing both an analysis step and a sorting step, such as the analysis and sorting (or isolating) steps in the Chandler method.

As to the following claims, Chandler discloses the limitations as follows.

As to claim 2, said large-capturing particles may be of different shapes (see Chandler col. 6, lines 18-21.)

As to claim 3, different types of molecules, cells or other particles can be bound to the large-capturing particles (col. 12, lines 58-61.)

As to claim 4, the large-capturing particles are covered with or bound to specific antibodies, parts of antibodies, oligonucleotides or other types of probes specific for the binding of the molecules, cells and other particles of interest (col. 12, lines 58-64.)

As to claim 5, the sample is simultaneously or sequentially incubated with two or more different sets of large-capturing particles for the isolation/depletion of two or more different types of molecules, cells or other particles from the sample (col. 24, lines 6-10, col. 17, lines 44-50, col., 12, lines 53-57, and col. 17, lines 3-9, and col. 4, lines 51-54.)

As to claim 6, each set of large-capturing particles can specifically bind one, two or more different types of molecules, cells or other particles from the sample (col. 12, lines 58-64.)

As to claim 7, the incubation of the sample with the large-capturing particles is performed by: (A) directly mixing the large-capturing particles with the sample (col. 14, lines 63-65, disclosing that a sample is combined with the microparticles.) (The combining step in Chandler is considered to be directly mixing the large-capturing particles with the sample.)

As to claim 8, the distinction between the large-capturing particles bound to the molecules, cells or other sample particles is based on their fluorescence (col. 15, line 52.)

As to claim 10, different sample volumes and amounts of large-capturing particles can be used in combination, (col. 16, lines 45-49.) Examiner notes that Applicant has not claimed from what the sample volumes and amounts of large-capturing particles are different. For examination purposes, Examiner interprets "different" to mean that the sample volumes and amounts of large-capturing particles can be any one of a variety of different volume or amount.

As to claim 12, the molecules are proteins (e.g., antibodies, col. 12, line 61.)

As to claim 13, the other particles are chromosomes, mitochondria, zymogen granules or cell membranes (col. 12, line 63, disclosing cell separation.) The cell separation disclosed by Chandler is considered to be a disclosure of sorting cell

membranes, since cells comprise membranes. In any case, the limitations in claim 13 refer to a limitation in claim 1 that is recited in the alternative (see claim 1, line 11.)

As to claim 14, the large particle is polystyrene (col. 3, line 23.)

As to claim 16, the sample is incubated in a chamber with two or more sets of large-capturing particles for the isolation of two or more different types of molecules, cells or other particles from the sample (col. 24, lines 6-10, and col. 17, lines 44-53.)

Response to Arguments

Applicant's arguments with respect to the newly added limitation regarding the chamber through which sample could be passed have been considered but are moot in view of the new ground(s) of rejection in view of Ollington et al.

With respect to Applicant's argument that there is no motivation to combine Chandler and Hansen, the Office is not persuaded by this argument because, as noted above, Chandler teaches that flow cytometry, in general, is the preferred method for analyzing and sorting the large-capturing particles and Hansen teaches a specific type of flow cytometer that allows for the convenience of both analyzing and sorting. Thus one of ordinary skill in the art would be motivated to use the flow cytometer taught by Hansen for the flow cytometry generally disclosed by Chandler for the convenience of both analyzing and sorting.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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07/01/05